

K964013

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**SUMMARY OF SAFETY AND EFFECTIVENESS
MITEK® ABSORBABLE TOGGLE ANCHOR**

SUBMITTER

NAME	Mitek Surgical Products, Inc.
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DATE	October 4, 1996

NAME OF DEVICE

CLASSIFICATION NAME	Staple, Fixation, Bone
COMMON NAME	Appliance for reconstruction of bone to soft tissue.

PROPRIETARY NAME	MITEK® ABSORBABLE TOGGLE ANCHOR
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PREDICATE DEVICE	MITEK® STEALTH ANCHOR™ MITEK® WEDGE ANCHOR
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DESCRIPTION OF THE DEVICE

FUNCTION

Fixation of USP #2 suture below bone surface using unique design, insertion techniques, and materials.

DEVICE DESIGN

The Mitek Absorbable Toggle Anchor is cylindrical/conical in shape with an overall length of 0.44" x 0.11" in diameter.

MATERIALS USED

The Mitek Absorbable Toggle Anchor is molded from Poly-lactiac (PLA).

INTENDED USE

SHOULDER

1. Rotator Cuff repair
2. Capsule shift/capsulo-labral reconstruction

KNEE

1. Extra-capsular repairs and reattachment of:
 - medial collateral ligament
 - lateral collateral ligament
 - posterior oblique ligament and joint capsule to tibia
 - joint capsule closure to the anterior proximal tibia
2. Extra-capsular construction, ITB tenodesis
3. Patellar ligament and tendon avulsion repairs

ANKLE

1. Achilles tendon repair/reconstruction

COMPARISON TO PREDICATE DEVICE

The Mitek Absorbable Toggle Anchor is similar to the Mitek Stealth and Wedge Anchor in materials and to all other Mitek Anchors in use and function, i.e., to "hold" tissue, with sutures that are locked into a predrilled bone hole, for a period of rehabilitation.

DESCRIPTION OF NON CLINICAL TESTS

Mitek Absorbable Toggle Anchor pull tests from cadaver bone provided an average failure load of 32 pounds.